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Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

September 8, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned submits this petition under applicable sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371] and 21 CFR 10.30 to request the Commissioner of Food and Drugs to amend the 21 CFR 101.36 and 21 CFR 101.100 to permit a manufacturer or distributor of dietary supplements to use the phrase "may contain" or "may also contain" on the label of a finished product to list ingredients that are not dietary supplements, or do not contain dietary ingredients, when these ingredients are sourced from multiple suppliers.

A. Action requested

The Consumer Healthcare Products Association (CHPA)[1] asks that FDA amend 21 CFR 101.36 and 21 CFR 101.100 to permit a manufacturer or distributor of dietary supplements who uses multiple suppliers to source a finished-form dietary supplement with different ingredients that are not dietary ingredients, or that do not contain dietary ingredients (e.g., excipients, fillers, artifical colors, artificial sweetners, flavors and binders) to use "may contain" or "may also contain" on the label of a finished product to list ingredients provided uniquely by certain suppliers.

[1] CHPA is the 119-year-old trade organization representing dietary supplements and nonprescription drugs, including over 200 members across the manufacturing, distributing, supply, research testing, and advertising sectors of the self-care industry.

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CHPA requests this action by FDA so that manufacturers and distributors will fulfill the requirement to disclose product ingredients, but have the needed flexibility to source product from more than one supplier without the expense of separate inventories and costly label changes.

CHPA's petition supports a similar Citizen Petition submitted on June 2, 2000, by Arnall Golden & Gregory, LLP.

B. Statement of grounds

1. Background

a. Overview of Relevant Characteristics of Dietary Supplement Production

A dietary supplement product is individually prepared and labeled to disclose the ingredients, distributor and other information specific to that product. Typically, dietary supplements are produced and shipped in short periods of time, with the principle of just-in-time inventory.

A dietary supplement company may often use multiple suppliers for ingredients in some products in order to maintain an uninterrupted supply of product to its customers. Short-term demands of suppliers can disrupt production schedules, thereby interrupting the flow of product from producer to retailer, resulting in extra costs.

The specific makeup of composite inactive ingredients can vary slightly from supplier to supplier. For example, different suppliers may use different lubricants or binders that are specific to their particular processes.

b. Regulatory Considerations

Under the Federal Food Drug and Cosmetic Act, a food is misbranded unless the product label bears, "in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient..." [21 USC 343(i)(2)]. If compliance with this requirement would be "impractical, or results in deception or unfair competition," FDA may grant an exemption [21 USC 343(S)]. A dietary supplement is misbranded if its label or labeling fails to list the name of each ingredient of the supplement [21 USC 343(S)].

Under 21 CFR 101.4(a)(1), ingredients are required to be declared on the label or in the labeling of a dietary supplement by listing each such ingredient by common name or usual

name, in descending order of predominance by weight on either the principal display panel or the information panel, although there are limited exceptions. Ingredients listed in the nutrition label of a dietary supplement do not have to be repeated in the ingredient list (21 CFR 101.36). FDA stipulates by 21 CFR 101.4(g) that:

> "When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word "Ingredients," unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words, 'Other Ingredients' Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, flavors, or binders, shall be included in the ingredient list."

FDA also requires that dietary supplements offered for sale provide nutrition labeling, unless an exemption applies [21 CFR 101.36(a)].

Specific exemptions to certain food labeling requirements exist, including exemptions from ingredient declaration: exemptions for foods that are being shipped for further processing; incidental additives; and foods that arrive at the retail establishment in bulk containers and displayed at retail in the bulk container with its labeling in plain sight or in connection with counter cards or signs (21 CFR 101.100). Other exemptions also exist relating to dietary supplements of low-volume [21 CFR 101.9(j)(1) and 101.9(j)(18)] or shipped in bulk form not for consumer distribution [21 CFR 101.9(j)(9)].

However, none of these exemptions apply to the object of this petition. As a result, CHPA requests FDA amend 21 CFR 101.36 and 21 CFR 101.100 to permit a dietary supplement manufacturer to include the phrase "may contain" or the phrase" may also contain" on a label of a finished dietary supplement product, when the manufacturer uses more than one supplier to source non-dietary ingredient in a dietary supplement product.

2. Rationale for Requested Amendment of 21 CFR 101.36 and 101.100

CHPA requests an amendment of 21 CFR 101.36 and 101.100 for the following reasons:

- From a consumer health and product use standpoint, ingredient labeling is included on labeling of dietary supplements to alert consumers to ingredients to which he or she may have an allergic reaction or other adverse effect or which the consumers wishes to avoid

on the basis of personal preference. The only drawback to labeling containing the phrase "may contain" (or "may also contain") would be that the consumer will not purchase a self-care product with a label containing the phrase "may contain" (or "may also contain") because of a listed ingredient, even though the product may not contain the ingredient of concern. However, in this case the consumer would not be without alternatives, as most, if not all, dietary supplements are marketed against competing products with different formulations, thereby allowing consumers to self-select to their needs.

- The use of the phrase "may contain" is not without precedent in the food and OTC arenas.
- "May contain" has been a phrase that has had practical use in the OTC marketplace through the successful CHPA voluntary ingredient program for OTC drugs that was in use over a period of 13 years. FDA has commended the industry for this voluntary labeling effort a number of times.
- Fat and oil ingredients not present in a food product do not have to be listed "if they may sometimes be used in the product" [21 CFR 101.4(b)(14)]. These ingredients are identified by words indicating that they may not be present, such as "or," "and/or," and "contains one or more of the following" [21 CFR 101.4(b)(14), (16-19)].
- Without the ability to use the phrases "may contain" or "may also contain" a company would incur excessive costs through impractical use of resources. Specifically, were a company not able to use these phrases, it would:
  - Have to purchase from one supplier, running the risk of product shortages due to a supplier's problems with its production process or with meeting higher than forecasted retail demands;
  - Have to carry separate inventories of packaging and labeling materials for the same product, with attendant substantial economic impact of maintaining adequate warehouse space to store all the materials, establishing new shelf keeping units (SKU's) and inventory controls, creating and retaining the supportive documentation

as well as supporting additional personnel to maintain duplicate labeling and packaging inventories.

- The effect of not amending the regulations is a de facto requirement that different suppliers would have to manufacture ingredients to an exact formula. This is impractical, since each supplier has specific experience with its own equipment, raw material sources, and methods of compounding and processing these materials, any and all of which may differ from those of another suppliers.

C. Environmental Impact

Under 21 CFR 25.30(j) and (k), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment

D. Lack of Economic Impact and Compliance Date

FDA specifies that specific economic information is to be submitted only when requested by the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

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Attachment 1984 CHPA Voluntary Ingredient Labeling Program (reprinted 1996)

WS/LS/WSjkq:DIETSUPP/LABELING/CitPet DS IngredLabelingfinal9/7/00

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Guidelines for OTC Labeling

Disclosure of Inactive Ingredients

The manufacture of nonprescription, over-the-counter (OTC) medicines is a science which requires the use of both active and inactive ingredients. Active ingredients produce the therapeutic effect. Inactive ingredients provide the "delivery system." Among other necessary functions, inactive ingredients serve as flavors, colors, binders, lubricants and preservatives.

OTC labels are required by law to identify all active ingredients and to identify and list quantities of certain ingredients, such as alcohol, whether active or not. The Nonprescription Drug Manufacturers Association (NDMA) in 1984 adopted a voluntary program to identify for the consumer inactive ingredients used in OTC medicines. This identification is not required by law.

Inactive ingredients in OTC medicines have established histories of safe use. But a small percentage of people are sensitive to particular substances no matter how safe they are for the vast majority. The NDMA voluntary program for listing of inactive ingredients is a further effort by industry to enable these persons to identify the presence or absence of substances in OTC medicines which they may wish to avoid.

The guidelines for disclosure of inactive ingredients are as follows:

1. The package of an OTC medicine intended for retail sale (but including samples and institutional packages) should contain an alphabetical listing of its inactive ingredients, including colors. The listing should be prefaced by language such as "also contains," "other ingredients" or "inactive ingredients" so as to distinguish clearly between active and inactive ingredients.
2. The listing should be legible and visible to consumers at point of purchase.
3. A small product container (one with a total surface area of less than 12 square inches and which is not contained in an outer container, such as a carton) may list its inactive ingredients in accompanying labeling.
4. Flavors and fragrances may be listed as "flavors" and "fragrances."
5. Ingredients which may be but are not always present in a product should be identified by words such as "or" or "may also contain."
6. An ingredient whose identity is a trade secret need not be disclosed if the inactive ingredients list states "and other ingredients." For purposes of this guideline, an ingredient constitutes a trade secret if its presence confers a significant competitive advantage on its manufacturer and the identity of the ingredient cannot be determined using modern analytical technology.
7. The name of an inactive ingredient should be taken from the most current edition of the following reference works:
   (a) United States Pharmacopeia (USP)/ National Formulary;
   (b) United States Adopted Names (USAN) and USP Dictionary of Drug Names;
   (c) CTFA (The Cosmetic, Toiletry, and Fragrance Association) Cosmetic Ingredient Dictionary; and
   (d) Food Chemicals Codex.

   An ingredient not listed in any of the above references should be identified by the name generally recognized by consumers or, if none, the chemical or other technical name.
8. Incidental ingredients which are present in the product at insignificant levels and that have no technical or functional effect need not be identified, unless the omission of the incidental ingredient would constitute a failure to reveal a material fact.

The effective date for voluntary compliance with these guidelines was December 1, 1985.

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